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August 1, 2023

**VIA ECF**

The Hon. Robert B. Kugler  
United States District Judge  
USDJ, District of New Jersey  
Mitchell H. Cohen Building & U.S.  
Courthouse  
4th & Cooper Streets, Room 1050  
Camden, NJ 08101

Special Master the Hon. Thomas  
Vanaskie  
Stevens & Lee  
1500 Market Street, East Tower, 18th  
Floor  
Philadelphia, PA 19103

RE: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK-KMW (D.N.J.)

Dear Judge Kugler and Judge Vanaskie:

I write on behalf of the Defendants' Executive Committee to inform the Court that defendants wish to address three agenda topics at the conference with the Court on August 3, 2023, and to set forth our positions on those items.

**Losartan/Irbesartan Discovery**

The parties have met and conferred regarding plaintiffs' discovery and discussed potential issues applicable to all losartan/irbesartan manufacturer defendants ("manufacturer defendants" or "defendants"). (See Exhibit 1, M. Goldenberg email chain with S. Harkins.) The parties have come to agreement on a number of issues, but do not agree on the overall schedule for all manufacturer

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defendants' production of losartan/irbesartan documents, and therefore request the Court's guidance regarding the production schedule issue.<sup>1</sup>

The manufacturer defendants involved in losartan/irbesartan discovery include some parties that participated in valsartan discovery (Aurobindo, Hetero, Teva, Torrent, ZHP), and a number that have not previously engaged in any discovery or document production (Macleods, Sciegen, Vivimed). The manufacturer defendants that have not previously participated in any discovery are necessarily addressing issues such as custodians, search terms, ESI, and non-custodial document collection for the first time. Moreover, even the manufacturer defendants that previously participated in valsartan discovery are differently situated based on whether (and to what extent) they were involved in the manufacture of losartan, irbesartan, or both, and whether the same facilities, custodians, and search terms utilized for valsartan discovery are similarly appropriate for losartan and/or irbesartan. In light of these differences, manufacturer defendants proposed on June 20, 2023, and July 12, 2023 that plaintiffs consider separate production schedules by manufacturer defendant or category of manufacturer defendants to account for these individual circumstances. Plaintiffs have considered and declined, expressing that they want a single production schedule applicable to all responding manufacturer defendants.

Manufacturer defendants proposed the below production schedule, which accounts for the time needed to finalize disputes and present them to the Court on August 31, 2023, resolve those disputes in the following weeks, and engage in voluminous custodial and non-custodial document review and production. Because plaintiffs have stated multiple times that they want one schedule for all responding manufacturer defendants, the proposed schedule must take into account the different circumstances of each of those manufacturer defendants described above. The following schedule takes those circumstances into account.

- August 31, 2023: Deadline to submit disputes regarding written discovery, search terms, and custodians to the Court; outstanding issues to be argued before Judge Vanaskie at the September Biweekly Conference Call
- February 1, 2024: Deadline to produce noncustodial documents
- April 30, 2024: Deadline to complete custodial production

The production schedule that the manufacturer defendants propose is substantially shorter than the nearly year-long production of valsartan documents, which followed many months of negotiations and briefing over custodians and search terms. Manufacturer defendants have proposed an approximately 45-day schedule to address disputes and an eight-month schedule for production – several months less than the time taken for the Valsartan document production. This schedule cannot possibly prejudice plaintiffs at this initial stage of developing the irbesartan and losartan cases. Notably, some manufacturer defendants, particularly those that have previously participated

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<sup>1</sup> The parties continue to meet and confer regarding defendant-specific issues (e.g., custodians, search terms, scope, etc.) and have agreed that any defendant-specific disputes will be presented to the Court by August 31, 2023. (*See Ex. 1.*)

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in valsartan discovery, will begin producing documents this month, and plaintiffs will therefore have materials to begin to review early in the schedule. Moreover, plaintiffs are already in possession of the material produced as part of losartan core discovery, which was substantially expanded from valsartan core discovery to include sales and pricing information, testing information, and facility inspection documents.

Plaintiffs' proposed schedule would require all responding manufacturer defendants to complete non-custodial productions by October 31, 2023, less than two months after any dispute over non-custodial productions submitted to the Court on August 31, 2023, will have been resolved. (*See* Ex. 1.) The proposed deadline of December 31, 2023 for completion of custodial discovery would allow less than four months for a massive custodial review. (*Id.*) Prior experience in valsartan discovery and any reasonable analysis of the volume of material to be reviewed make clear that this is not a workable timeline.<sup>2</sup>

With respect to oral discovery, consistent with the scheduling approach for valsartan discovery, manufacturer defendants believe it is unnecessary and premature to set deadlines for depositions of corporate 30(b)(6) witnesses, expert witnesses, class representatives, or individual losartan/irbesartan plaintiffs at this time. Manufacturer defendants recognize that these depositions will need to be taken, and they will work with plaintiffs to complete those phases in an efficient manner. However, we note that in the valsartan cases, scheduling of the first subsequent phase – designation and depositions of corporate 30(b)(6) witnesses – did not take place until the parties had substantially completed custodial document production.

Manufacturer defendants similarly believe it is premature to set deadlines for expert briefing as plaintiffs propose, and this is especially true given the absence of guidance on whether those experts would be addressing general causation, class certification, liability, and/or damages issues.

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<sup>2</sup> In connection with the meet-and-confer process, manufacturer defendants offered the following compromise schedule that plaintiffs also rejected:

- August 31, 2023: Deadline to submit disputes regarding written discovery, search terms, and custodians to the Court; outstanding issues to be argued before Judge Vanaskie at the September Biweekly Conference Call
- December 15, 2023: Deadline to produce noncustodial documents
- February 28, 2024: Deadline to complete custodial production

As explained to Plaintiffs on July 12, 2023, manufacturer defendants proposed this schedule with the caveat that they might need to come back to the Court to seek more time if the compromise schedule turned out to be too compressed. Manufacturer defendants believe that their original proposed schedule, as discussed above, is a more appropriate schedule, particularly in light of the fact that they offered this compromise nearly one month ago and some core issues that would affect this schedule still have not been resolved with plaintiffs.

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Accordingly, the responding manufacturer defendants request that the Court enter an order memorializing the above production deadlines, after which the parties will meet and confer to discuss deadlines for subsequent phases of discovery, as appropriate.

### **Update on Retailers' and Wholesalers' Productions Under CMO No. 32**

#### **The Pharmacy Defendants' Productions Under CMO No. 32**

CMO 32 ordered the Pharmacy Defendants to produce three categories of discovery:

- (1) the amounts TPPs paid for valsartan products at issue in this litigation;
- (2) the Pharmacy Defendants' costs and profits for VCDs; and
- (3) previously-redacted retailer identifiers of ConEcoLoss members.

As the Court is aware, the Pharmacy Defendants met and conferred with Plaintiffs to define the scope of the productions numerous times, involving the Court in those discussions as appropriate.

Regarding the third item, the Pharmacy Defendants are working diligently to produce data reflecting the names and available contact information for the ConEcoLoss members by August 21, 2023, as required by the Amended Protected Health Information Order. (*See* Dkt. No. 2434.)

Regarding TPP payments and cost and profits data, the parties agreed that the Pharmacy Defendants would provide that information by answering a set of negotiated interrogatories. The parties agreed to the language of the interrogatories with the exception of one issue, which was briefed and argued before the Special Master on June 23, 2023. (*See* Dkt. Nos. 2427, 2432, 2440 (the parties' briefing on this issue).) Once this is ruled on and entered by the Court, the Pharmacy Defendants will serve responses to plaintiffs' interrogatories within 60 days.

#### **The Wholesaler Defendants' Productions Under CMO No. 32**

Wholesaler Defendants have produced the pricing data responsive to CMO 32 sections 7.1.2 and 7.1.3. With respect to the costs and profits data referenced in section 7.1.1, at plaintiffs' suggestion, Wholesaler Defendants continue to work to develop a proxy formula for approximating profit data regarding VCDs because, as they previously advised plaintiffs and the Court, Wholesaler Defendants do not, in the ordinary course of business, calculate or maintain profit information on VCDs either on an NDC basis or individual transaction basis. In that regard, Wholesaler Defendants now have identified and retained consultants who are currently working to evaluate data and a potential proxy formula(s). Progress on this process is ongoing. With respect to a schedule for the targeted discovery of Wholesaler Defendants' custodians regarding valsartan referenced in CMO 32 section 7.2, Wholesaler Defendants made a proposal to plaintiffs on July 14, 2023, that included a combined schedule for all custodial discovery

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regarding valsartan, losartan, and irbesartan. Given plaintiffs' requests for discovery regarding losartan and irbesartan served on May 22, 2023, Wholesaler Defendants believe it is most efficient and cost effective to negotiate, conduct, and complete custodial discovery (which involves significant e-discovery efforts) at the same time and on the same schedule for all three products. Moreover, as plaintiffs acknowledged in their April 12, 2023 letter to the Court requesting targeted custodial discovery related to valsartan, there is no pressing need to complete valsartan-related custodial discovery such that it would need to be completed separate or apart from custodial discovery on losartan and irbesartan. Plaintiffs responded to Wholesaler Defendants' July 14, 2023 proposal on July 24, 2023, and Wholesaler Defendants responded with an amended proposal to plaintiffs on July 31, 2023. The parties are continuing to meet and confer and negotiate on that proposal, including the schedule for custodial discovery related to all three products.

### **PFS Deficiencies and Orders to Show Cause**

#### **Cases Addressed at the June 7, 2023 Case Management Conference:**

The Court issued five show cause orders returnable at the August 3, 2023 Case Management Conference:

1. *Diane Hardwick v. Aurobindo, et al.* – 22-cv-6397
2. *Rafael Feria v. Teva, et al.* – 23-cv-485
3. *Robert Janeczek v. ZHP, et al.* – 23-cv-538
4. *Jacquelyn Smason v. Doe, et al.* – 23-cv-194
5. *Ricky Young v. ZHP, et al.* – 22-cv-7210

The issues in the *Hardwick*, *Feria*, and *Janeczek* matters are resolved, and the show cause orders may be withdrawn.

The issues in the *Young* and *Smason* matters remain unresolved, but the parties agree to an extension of the show cause orders until the next case management conference.

#### **Second Listing Cases – Order to Show Cause Requested:**

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these cases were previously listed on the agenda for a prior CMC. This list was provided to plaintiffs' leadership on July 25, 2023, and a global meet and confer was held on July 28, 2023. Defendants have also been available for further discussion as needed. Accordingly, defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why these cases should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the August 3, 2023, Case Management Conference:

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Leslie Sturgill v. ZHP, et al.	23-cv-612	Bernstein Liebhard LLP	Largely deficient PFS, no records.	5/2/23
2.	Taffnie Williams v. Aurobindo Pharma, et al.	20-cv-20380	Donahey Law Firm	Need pharmacy records; need undated healthcare authorizations	5/3/23
3.	Sharon Thomas v. Aurobindo Pharma, Ltd. et al.	23-cv-0338	Nigh Goldenberg Raso & Vaughn	No medical expense records uploaded; declaration is undated and is missing Plaintiff's printed name; necessary authorizations are signed but incomplete.	4/11/23
4.	Joseph George v. Hetero, et al.	21-cv-12916	Goldenberg Law, PLLC	No Amended PFS Filed  Largely deficient PFS; insufficient product ID information and background information; no response as to potential wage loss claim; no authorizations; pharmacy records; no signed declaration  Missing medical records from Kennersville VA	5/20/23

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
5.	Michelle Worms v. Hetero Labs, et al.	20-cv-19852	Goldenberg Law, PLLC	No Amended PFS Filed  Largely deficient PFS; insufficient product ID information and background information; no response as to potential wage loss claim; no authorizations; no medical or pharmacy records; no signed declaration;	5/11/23
6.	Robert Lee v. Hetero Drugs, et al.	20-cv-19843	Nigh Goldenberg	III.3 – Plaintiff identifies his last date of usage for Losartan products was in March 2019. As such, please identify how Plaintiff has managed or treated his hypertension after discontinuing the use of Losartan products.  X.I – No health care authorization was produced for: 1) Orlando Health; 2) Underwood Surgery Center; 3) Central Florida Hospitalist Partners; 4) Florida Hospital Medical Center; 5) or Sand Lake Imaging. Please produce properly executed and undated authorizations for said providers.  X.6 – No insurance records authorization was produced for: Florida Blue. Please produce a properly executed and undated authorization for said carrier.	5/10/23

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
				X.2 – No pharmacy records produced for: 1) CVS; or 2) CVS Specialty Pharmacy.  No executed declaration produced with Second Amended PFS.	
7.	Karl Bartels v. Hetero Labs, et al.	20-cv-19869	Nigh Goldenberg	Largely deficient PFS, need records.	5/11/23
8.	Seifert v. Mylan Pharmaceuticals, Inc., et al	22-cv-06727	Brown Chiari LLP	Incorrect date on declaration (states that it was signed in 2013); areas of PFS left blank, see notice for complete listing	5/30/2023
9.	Tom Lemen v. ZHP, et al.	21-cv-740	Law Office of Oscar Alvarez	No PFS Filed	PFS Due – 4/2/21
10.	James Magee v. ZHP, et al.	19-cv-15858	Pro Se	No PFS Filed	PFS Due – 11/18/19



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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
11.	Phyllis Axt v. ZHP, et al.	20-cv- 8050	Douglas & London	No PFS Filed	PFS Due – 9/1/20
12.	Beatrice Meza v. Hetero, et al.	20-cv- 8799	Wiggins Childs	No PFS Filed	PFS Due – 9/13/20
13.	Arnold Vander v. ZHP, et al.	20-cv- 10244	Rubin & Machado, Ltd	No PFS Filed	PFS Due – 10/19/20
14.	E/O Barbara Lipscomb v. Rite Aid, et al.	21-cv- 6574	Carlson Law	No PFS Filed	PFS Due – 5/24/21
15.	Benjamin Andrews v. ZHP, et al.	21-cv- 10908	Whitehead Law Firm	No PFS Filed	PFS Due – 7/7/21

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
16.	James Polk v. ZHP, et al.	21-cv-13582	Douglas & London	No PFS Filed	PFS Due – 9/12/21
17.	Tina Schram v. ZHP, et al.	21-cv-17384	Hollis Law	No PFS Filed	PFS Due – 11/22/21
18.	Boyko Achkova v. Rite Aid, et al.	21-cv-10355	Johnston Szykiel	No PFS Filed	PFS Due – 9/26/21
19.	Dean Tasman v. ZHP, et al.	23-cv-1399	Levin Papantonio	No PFS Filed	PFS Due – 5/13/23

**First Listing Cases – Remaining Core Deficiencies:**

The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved. This list was provided to plaintiffs' leadership on July 25, 2023, and a global meet and confer was held on July 28, 2023. Defendants have also been available for further discussion as needed. This is the first time these cases have been listed on this agenda. Accordingly, defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
1.	Tommy Benton v. Teva, et al.	21-cv-13858	Serious Injury	Largely deficient PFS. No records, no authorizations.	4/13/22
2.	Jerome Zimmerman v. ZHP, et al.	23-cv-1884	Chaffin Luhana LLP	No medical records. No pharmacy records. Authorizations must be undated	6/8/23
3.	Estate of Vincent Thompson v. Walmart, et al.	21-cv-6017	Carlson Law Firm	Information from records must be placed into fact sheet, generally referring to records is not sufficient response. Need authorizations.	6/8/23
4.	Ronald Jackson v. Torrent, et al.	23-cv-2341	Nigh Goldenberg	Need medical expenses, need pharmacy records, need medical records.	6/30/23
5.	Byron Wrigley	23-cv-831	Nigh Goldenberg	Largely deficient PFS. No authorizations. No records.	6/9/2023

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
6.	Steven Petrie	23-cv-1772	Fleming Nolen & Jez	Need medical expense records.	6/15/2023
7.	Gregory Adams v. Hetero, et al.	20-cv-15420	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
8.	Antonio Guzman v. Aurolife, et al.	20-cv-15712	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
9.	Lori Stratton v. Torrent, et al.	20-cv-15476	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
10.	Lawrence Taliaferro v. Camber, et al.	20-cv-15479	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
11.	Darlene Barzee v. Aurolife, et al.	20-cv- 15731	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
12.	Shirley Black v. Torrent, et al.	20-cv- 15740	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
13.	Anthony Burton v. Aurolife, et al.	20-cv- 15742	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
14.	Lillian Ghrigsby v. Aurolife, et al.	20-cv- 15746	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
15.	Dianne Hardy v. Aurolife, et al.	20-cv- 15748	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
16.	Robert Henley v. Huahai, et al.	20-cv- 15750	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
17.	Rhonda Kent v. Hetero, et al.	20-cv- 15752	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
18.	Arthur Smith v. Hetero, et al.	20-cv- 15757	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
19.	Jesus David Torres v. Hetero, et al.	20-cv- 15758	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21
20.	Joy Higgins v. Hetero, et al.	20-cv- 15759	Wiggins, Fairchild	No PFS Filed	PFS Due – 5/19/21

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
21.	Gonzalo Salazar v. Hetero, et al.	21-cv- 20033	Nachawati Law Group	No PFS Filed	PFS Due – 1/17/22
22.	Dinah Brown v. Camber, et al.	21-cv- 14477	Serious Injury	No PFS Filed	PFS Due – 3/20/22
23.	Jonathan Lee Swiger v. Hetero, et al.	21-cv- 19310	Houssiere Durant	No PFS Filed	PFS Due – 12/26/21
24.	Rosanne O’Callaghan v. Aurobindo, et al.	20-cv- 15125	Sizemore Law Firm	No PFS Filed	PFS Due – 12/28/20
25.	Shawna Martinez v. Aurobindo, et al.	21-cv- 12152	Arnold Itkin	No PFS Filed	PFS Due – 8/4/21

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	Plaintiff	Civil Action No.	Law Firm	Deficiencies	Deficiency Sent
26.	Emmett Wesson v. Aurobindo, et al.	23-cv- 2342	Nigh Goldenberg	No PFS Filed – Blank PFS filed	PFS Due – 6/27/23
27.	E/O Barbara Kaluhiokalani v. Hetero, et al.	23-cv- 2550	Nabers Law	No PFS Filed	PFS Due – 7/10/23
28.	E/O Mary Hines v. ZHP, et al.	23-cv- 2674	Nabers Law	No PFS Filed	PFS Due – 7/24/23
29.	Dixie Buxton v. Aurobindo, et al.	23-cv- 2933	Fleming Nolen	No PFS Filed	PFS Due – 7/30/23
30.	Pauline Harris v. Aurobindo, et al.	23-cv- 3016	Levin Papantonio	No PFS Filed	PFS Due - 8/1/23



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**Valisure Subpoena**

The parties completed briefing on Defendants' Motion To Compel Motion To Compel Materials In The Possession Of Third Party Valisure LLC (Dkt. Nos. [2217](#), [2227](#)) and Plaintiffs' Cross-Motion For A Protective Order (Dkt. Nos. [2228](#), [2248](#)) on January 23, 2023. These motions were also discussed at the January 19, 2023 Status Conference. (*See, e.g.*, Dkt. No. [2256](#).) Defendants would appreciate the Court's consideration of the issues raised in these motions.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Jessica Davidson".

Jessica Davidson

cc: All counsel of record (via ECF)